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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/509,262

05/11/2005

Mark S. George

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09/09/2010

Ballard Spahr LLP

SUITE 1000

999 PEACHTREE STREET

ATLANTA, GA 30309-3915

EXAMINER

GETZOW, SCOTT M

ART UNIT

PAPER NUMBER

3762

MAIL DATE

DELIVERY MODE

09/09/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/509,262	GEORGE ET AL.	
	Examiner	Art Unit	
	Scott M. Getzow	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 15-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 15-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Claim Rejections - 35 USC § 103

1. Claims 1-10,15-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fox et al (7,087,008).

The methods steps of the above claims are considered to follow obviously from the normal usage of the Fox device. For example, re claim 1, col. 5:28+ of Fox teach generating a fMRI to produce a function-image derived model of the patient's brain. Step 'a' of claim 1 is considered to be inherently performed by the use of fMRI. For example, the patient may be asked to move his thumb during the procedure. The location in the brain corresponding to the area controlling the thumb is then shown in the fMRI. Col. 6 of Fox teaches that a robotic arm, including the TMS coils, is automatically positioned over the area of interest, found during the fMRI procedure. See also, col. 22:20+ which teaches that the desired site is found via fMRI. The Fox device then delivers the TMS, which is known to cause 'neuronal depolarization', see col. 1:37 of Fox. The application of TMS is considered to inherently effect a change in a predetermined task. For example, it is known that application of TMS can be used to 'effect' a thumb twitch, col. 10:39. Also, col. 12:21+ teaches application of TMS to produce a contraction of the 'abductor pollicis brevis'. Thus, it is considered to be obvious to the skilled artisan that application of TMS would effectuate a change in a predetermined task. For example, the patient may be able to move a finger or limb more easily after TMS, than before (during the original fMRI procedure). Further, the phrase 'effectuating a change' in applicant's claims is considered to be broad; even the slightest of changes would be considered to be a change. Further, col. 7:60+ of Fox

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teaches that TMS results in 'behavioral effects'. Re claim 8, as mentioned above, TMS is known to affect behavior of a patient, and thus the behavior of at least one cognitive neural circuit. Step 'a' of claim 8 is considered to not limit the claim in any meaningful way over that of claim 1. The term 'behavior' is considered to be a broad term that would encompass any observable change in the patient's actions. Re claim 15, col. 14:35+ of Fox teaches the use of a robot that is controlled by the use of a PC. It is considered to be obvious/inherent that such PC has a CPU, or microprocessor, in that they are commonly used to control computerized devices. No unexpected results would occur from the use of a CPU. See also col. 17:27+ which teaches the use of a on-board controller, and a supervisory controller, and col. 22:55+ which teaches the use of various types of computers, all of which must have a CPU in order to operate. Further, the use of a power supply to supply power to the CPU is also obvious; otherwise the computers that are controlled by the CPU could not operate. Further, col. 5:45+ teaches that a function/anatomical model, produced by fMRI, is stored 'for subsequent use'. Such models are considered to be maps of the location of the desired sites to be stimulated. Also, col. 14:55+ teaches functional mapping. Still further, claim 1 of Fox teaches that a computer stores a pre-specified treatment plan in memory. Claim 12 of Fox teaches that instructions are stored that enable the controller to move the magnetic stimulator to a 'plurality of predetermined sites' of a patient. Thus, Fox is considered to teach that such instructions, or maps, are stored for a variety of potential stimulation locations, and that the robot arm can move to stimulate all of the different sites 'without user involvement'. Re claim 3, steps 'c', 'd', 'e' and 'f' are essentially the same as

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those of claim 1, as discussed above. Re steps 'a' and 'b' of claim 3, step 'a' can be considered to be a purely 'mental step'. Also, such step could be a simple dividing of patients who will be treated in the morning from those that will be treated in the afternoon. Thus, one patient will be treated in the morning and another will be treated in the afternoon. Such step is considered to not produce any unexpected results, but rather be the typical manner of performing therapy to a plurality of patients. Further, step 'b' could be fairly interpreted as having the 'first' state be the same as the 'second' state. The claim does not recite that the states are different. Further, step 'b' is further defined in applicant's claim 5, where it is set forth that one state is 'at rest' and the other state is 'sleep-deprived'. The term 'at rest' could mean that the patient is sitting down in a chair. The term 'sleep-deprived' is a broad term, and a subjective term, and, it is submitted, would encompass most people. Thus, the person sitting in the chair could also be sleep-deprived, and thus the two states could be the same. Re the dependent claims, such are considered to be encompassed by the teachings of Fox. For example, having the subject be a human is clearly set forth in Fox. Also, the use of a battery is known in the art. Laptop computers are typically powered by batteries. Re claim 20, col. 16:24+ teaches a cart, which is clearly portable. Re claim 21, col. 8:25+ of Fox teaches the use of two coils. To be able to deliver stimulation via one or both would not produce any unexpected results. Re claims 22,23, to apply stimulation to improve a patient's condition is considered to be obvious. One of ordinary skill in the art would want to improve the patient's condition, rather than worsen it.

2. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott M. Getzow whose telephone number is (571) 272-4946. The examiner can normally be reached on M-F, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Niketa Patel can be reached on (571) 272-4156. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Scott M. Getzow/
Primary Examiner, Art Unit 3762